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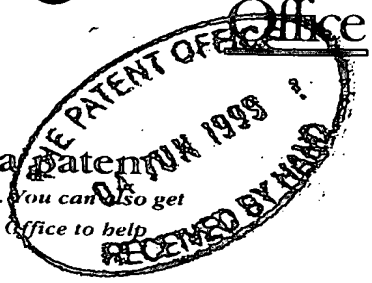

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference

DCW/VSW

04 JUN 1999

2. Patent application number
(The Patent Office will fill in this part)

9913100.5

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Denfotex Ltd.
Wyndham
Hophurst Hill
Crawley Down
West Sussex, RH10 4LP

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

7613338001

4. Title of the invention

"Method and apparatus for filling a dental root canal"

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Brookes & Martin

High Holborn House
52/54 High Holborn
London WC1V 6SE

Patents ADP number *(if you know it)*

471001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

yes

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	10
Claim(s)	2
Abstract	
Drawing(s)	1 + 1

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Brookes & Martin Date 4 June 1999

BROOKES & MARTIN

12. Name and daytime telephone number of person to contact in the United Kingdom

0171 242 9631 - David C. Woodcraft

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METHOD AND APPARATUS FOR FILLING A DENTAL ROOT CANAL

This invention relates to the treatment of a dental root canal including the obturation of the canal.

Background of the Invention

There are a number of causes of endodontic treatment of teeth. The tissue lying within the tooth structure, the dental pulp, may become diseased as a result of dental caries or the cells and tissue may be traumatised or atrophy. As a result of this, the pulp tissue may become infected. This leads to death of the pulp. The treatment of choice is the removal of the diseased tissue and achieving a cell and bacteria free root canal using mechanical methods of tissue removal. These operations are technically difficult and require the accessing of the canal and removing infected tissue, which may be at or near the apex of the root of the tooth. The treatment becomes more complex as the anatomy of the root canal becomes more complex and the canals themselves become narrower.

Conventional treatment involves gaining access to the pulpal chamber by removing the overlying enamel and dentine. Once the chamber is exposed, the entrances to the root canals are then enlarged. The length of the root canal is calculated from a diagnostic radiograph and the canal is instrumented using files and reamers of increasing size. These instruments are designed to remove the internal surface of the root canal by rasping and cutting the dentine walls. The dentine walls have small holes where the cell processes track into the dentine. These holes are sites where bacteria can settle and proliferate. It is these areas which are reduced by

mechanical debriding of the internal surface of the root canal. To achieve this, the reamers and files are used to produce a root canal that, near the apex, is matched in size to the obturating device. The internal diameter of the canal is enlarged so that the cavities in the root wall are reduced in size and the canal is mechanically cleaned.

Medicaments may be used to chemically kill the bacteria; these are usually disinfectants such as hypochlorite or antibiotic pastes. These may be introduced into the root canal after initial mechanical debridement. These medicaments and mechanical methods of removal of tissue are designed to produce a root canal which is free of bacteria and other contaminants. Conventional procedures are time consuming and difficult to carry out. The more posterior the tooth situation within the mouth the greater the risk of failure to achieve the objectives, since the root canals morphology becomes more convoluted and access becomes more difficult to achieve.

Summary of the Invention

An important objective of the present invention is to simplify the treatment of dental root canals and to provide a treatment system which enables the dentist to be more confident that remnants of decay within the canal have been dealt with.

Another object is to reduce the time normally required to prepare a root canal for obturation and also to provide a system of obturating the canal which is co-ordinated with the preparation of the canal.

According to one aspect of the invention there is provided a method of treating a dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to laser light via an optical fibre within the root canal, said optical fibre being effective to illuminate a substantial part of the root canal; and

(d) sealing the root canal, preferably by introducing a curable filling material into the root canal.

Although the root canal may be sealed with a conventional obturator (e.g. as described in EP-A-0337024), it is preferred to seal the root canal with a curable filling composition, especially a light-cured filling composition.

In a preferred arrangement, the light-curable filling composition is cured by irradiation by laser light introduced through an optical fibre positioned within the root canal. The optical fibre is generally provided with an isotropic distal tip and may be the same optical fibre that is used to guide laser light into the canal to activate the photosensitiser. After the filling material has been cured, the optical fibre may remain entombed in the root canal as part of the obturation.

The invention also includes a kit of parts for treating a dental root canal which comprises:-

(a) a flowable photosensitiser;

(b) an optical fibre having an isotropic distal tip and adapted for introduction into a root canal so that the tip is capable of reaching the region of the apex of the root canal, said optical fibre being connectable proximally with means for generating laser light; and

(c) a flowable curable filling composition capable of introduction into the root canal and filling the canal.

It will be appreciated therefore that the invention makes use of a combination of a photosensitive substance and a light source operating at the appropriate wavelength to activate the photosensitiser. A further aspect of the invention is the delivery mechanism, which permits the delivery of the photosensitiser either at or near the apex of the root canal to ensure that the photosensitiser will contact the debris and bacteria. A further element is the provision of a novel sealing or filling material, which will prevent re-infection of the canal from either the access cavity or via the apical foramen. The sealing or filling material may be delivered via the novel delivery system.

The root canal is accessed in the normal way using a high speed dental drill. Alternatively, a laser may be used to expose the pulpal chamber and the entrance to the root canal. It is not, however, necessary to mechanically ream the walls of the root canal to remove infected sites within the dentine. Instead, a photosensitiser is introduced into the root canal. This may be achieved using a fine tipped syringe or, alternatively, with a specialised dispensing accessory as described below.

After introducing the photosensitising agent into the root canal in the tooth, the agent is actuated using light delivered by an optical fibre from a laser. The wavelength employed depends on the absorption spectra of the photosensitiser. Toluidene blue O is preferably employed as the photosensitiser and has an absorption maximum in the range of 600~700 nm. Semiconductor lasers, gallium/arsenide and

helium/neon lasers may be used. The laser light may be continuous or pulsed. It has been found to be important to spread the laser light within the bore hole rather than focus it on a small target area. One way of achieving this is to provide an optical fibre which terminates in an isotropic tip, e.g. a generally spherical tip. A method of forming such a tip is described in US Patent No. 5,073,402.

The Photosensitiser

The photosensitiser is used for the disinfection of the internal surface of the root canal by placing a liquid or gel in contact with the debris and bacteria. The interior of the root canal is then irradiated with light of an appropriate wavelength that will be absorbed by the photosensitiser.

In preferred aspects of the invention, the photosensitiser and laser combination may be applied to:-

(a) disinfection or sterilisation of the root canal after initial access has been gained to the root canal of the infected tooth;

(b) destruction of carious microbes on the internal root surface in order to prevent reinfection.

Photosensitising agents used in this invention are generally non toxic to the target microbes in the concentrations envisaged or to the surrounding tissue. However, there is no requirement that the photosensitiser should not be toxic to the microbes. Since the exposure times are short, it may be acceptable to use compounds which have some slight toxicity to the tissue.

It is preferred that the photosensitisers used will be capable of absorption in the red end of the visible spectrum or at longer wavelength, as these wavelengths will have greater penetrating powers in the tissue surrounding the canal.

The preferred photoinitiators are those effective against Gram Negative bacteria associated with dental caries. These are the dyes. Of these, the currently preferred is Toluidene blue O. Alternatively, aluminium disulphonated phthalocyanine chloride, methylene blue or azure blue chloride may be used. While the dye may be non specific, it can be made specific to the microbes within the root canal.

The Laser

The concentration of photoinitator and laser power are matched to provide maximum penetration of tissue and kill rates.

The concentrations of dye range from 0.00001% to 2%. The currently preferred concentration is 0.001 to 1%.

The preferred laser irradiation time of the photosensitiser is between 2 seconds and two minutes and the preferred exposure time is between 10 seconds and 1 minute.

The laser power is preferably between 10-0 and 600 mW, the most preferred being 150 mW.

The light dose ranges from 5-30Jcm-2, preferably 10-20Jcm-2 and more preferably about 15Jcm-2.

The photosensitiser solution concentration may be influenced by any extrinsic fluid and concentration may be increased to compensate for this.

In order to enhance the penetration of hard tissue and to enable the photosensitising agents to have maximum effect, potentiating agents may be added to the photosensitising solution. These may include:-

- Acids to produce a solution pH of 4.5 or above
- Acids to penetrate and remove organic/inorganic debris
- Wetting agents such as HEMA (hydroxyethyl methacrylate) and glutaraldehyde
- Demineralising agents such as chelating agents of the type EDTA disodium.

Such materials may be citric acid, polyalkenoic and polyphosphonic acid, phosphoric acid, EDTA and HEMA or other such acids as are known for use in this technique.

A further addition to the photosensitising phase is the addition of demineralising solution to be applied with or subsequent to the application of the dye.

Suitable agents are described by Levine {} Causton and Newell Johnson {} or Pearse and Nelson Caries Research 1988, 22,362-370.

It is important that these agents do not interfere with the photosensitising process, in particular the use of free radical and singlet oxygen scavenging materials should be avoided.

The photosensitiser may be delivered by a syringe but more preferably by a thin flexible tube which is perforated along the final part of its distal end, e.g. the last 15 mm of its length. The perforated tube, whose diameter is preferably a maximum of

0.1 mm, will be inserted up as far as the apex of the root canal and the dye injected via a unit dose cartridge through the tube permitting the dye to coat the whole length of the walls of the root canal. The unit dose syringe and tube will then be removed and the fibre connected to the light source inserted into the canal. The photosensitiser dye will be activated by the light source.

The filling or sealing material

A further aspect of the invention is that a fluid sealing agent may be syringed up through the delivery system previously described. This will coat the walls of the root canal and may then be cured using a visible light source.

These may be resins such as those described as dental adhesives in Patent Application Nos. PCT/GB92/02128; PCT/GB98/00072; US 5,172,763 and US 5,063,257, and other curable resin systems which are employed as dental adhesive and filling materials. Preferably, the sealing or filling material is light-curable. The preferred resin system is one containing combinations of tetrahydrofurfuryl methacrylate (THFMA) and urethane dimethacrylate (UDMA) in the range of THFMA 30-90%. These resin systems will contain initiators such as α diketones and amines using a light source operating at 460-470nm.

Alternative materials such as sol-gel glasses may also be used as the sealing agents delivered in a similar manner to that described above.

The accompanying drawings illustrate the manner in which the invention may be carried into effect.

Figure 1 is a schematic cross-section through a tooth with an optical fibre in place in a root canal;

Figure 2 is a section of an enlarged scale of an optical fibre;

Figure 3 is a section through a single dose device for delivering a photosensitiser solution into the root canal.

The tooth (1) is first drilled to access the entrance (2) to the infected root canal (3), and loose debris suctioned away. A photosensitiser solution, e.g. toluidene blue, in aqueous solution is then introduced into the root canal using a fine-tipped syringe or a disposable dispenser such as shown in Figure 3. Referring to Figure 3, the dispenser comprises a thin-walled cannula (10) having a reservoir (11) for photosensitiser solution attached to its proximal end. The connection between the reservoir and the cannula is sealed with a frangible membrane 12. At its distal end, the cannula is perforated with small holes (13) which permit the escape of liquid from the cannula. In use, the cannula is inserted into the root canal until the distal end is close to the apex of the canal. Photosensitiser is discharged into the root canal by pressing on the reservoir (11), thus causing the membrane to rupture and liquid to flow out of the distal end and through the perforations (13). The perforations (13) ensure that the walls of the root canal are wetted with photosensitiser solution. The dispenser is then removed and an optical fibre (20), as shown in Figure 2, is introduced into the root canal (3).

As can be seen best in Figure 2, the optical fibre is formed with a distal spherical portion (21). This has the effect of diffusing light passed down the fibre

and ensures that light emerging at the tip (21) is scattered uniformly around and in upward and downward directions in the root canal.

After the photosensitiser has been irradiated with laser light for a sufficient period to ensure sterilisation of the interior of the canal (usually 30 seconds to 1 minute at a laser power of about 150 to 200 mW), the optical fibre is removed.

It may be desirable at this point to syringe excess photosensitiser from the canal. However, this may not be necessary, particularly when using a hydrophilic sealing composition in the subsequent step.

A fluid sealing or filling composition is then introduced into the canal. For this purpose, a unit dose dispenser such as that shown in Figure 3 may be used. An optical fibre such as shown in Figure 2 may then be introduced into the root canal and laser light passed down the fibre to cure the sealant material. This will hermetically seal the root canal from reinfection. The projecting part (24) of the optical fibre may then be cut off and the access hole (25) may be filled with a conventional dental filling material such as an amalgam or glass ionomer resin.

CLAIMS:-

1. A method of treating a dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to laser light via an optical fibre within the root canal, said optical fibre being effective to illuminate a substantial part of the root canal; and

(d) sealing the root canal, preferably by introducing a curable filling material into the root canal.

2. A method according to claim 1 wherein the curable filling material is cured by irradiation by light through an optical fibre within the root canal.

3. A method according to claim 2 wherein the same optical fibre is used for activating the photosensitiser and the curable filler material.

4. A method according to any one of the preceding claims wherein the optical fibre has a substantially isotropic tip.

5. A kit of parts for treating a dental root canal which comprises:-

(a) a flowable photosensitiser;

(b) an optical fibre having an isotropic distal tip and adapted for introduction into a root canal so that the tip is capable of reaching the region of the apex of the root canal, said optical fibre being connectable proximally with means for generating laser light; and

(c) a flowable curable filling composition capable of introduction into the root canal and filling the canal.

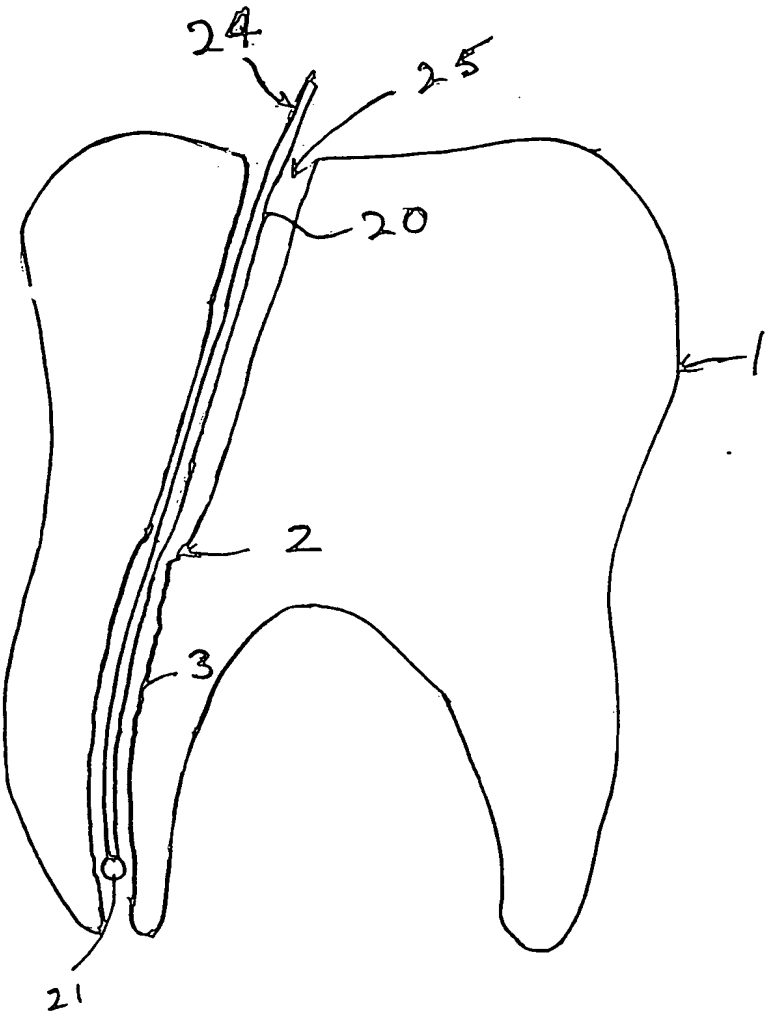


Fig 2

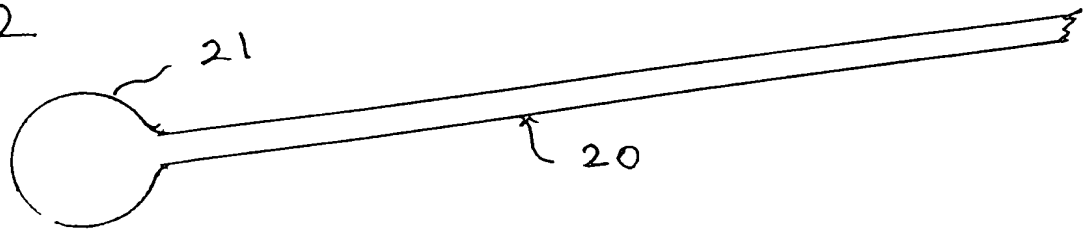
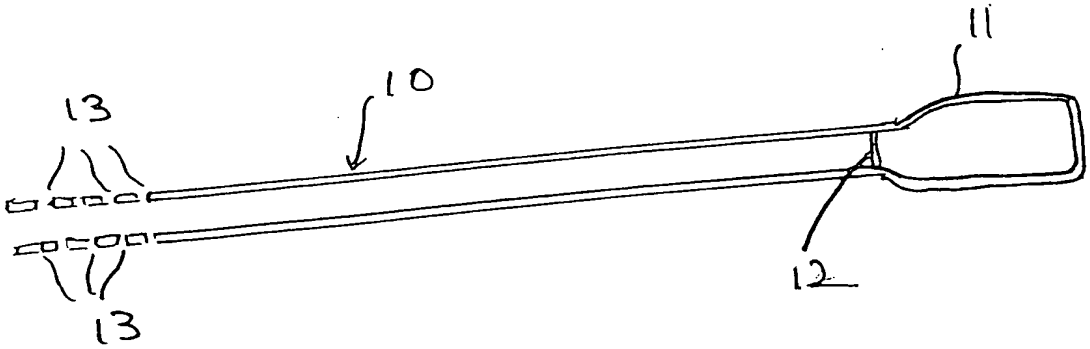


Fig 3



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